

## REMARKS

Non-elected claims 48, 49, 51, 52, 90 and 91 have been canceled. Thus, claims 1, 2, 9, 10, 15, 16, 19, 22, 23, 25-29, 31, 33, 36, 38, 41, 42, 44, 46, 54, 58, 60-89 and 92-96 are pending. Independent claims 1 and 92 have been amended to distinguish over the prior art of record. No new matter was added. Accordingly, Applicants respectfully submit that the present application is in condition for allowance.

### I. Claim Rejections - 35 USC §102(e)

In the Office Action, the Examiner rejects claims 1, 2, 9 and 10 under 35 USC §102(e) as being anticipated by U.S. Patent No. 6,130,098 issued to Handique et al.

Handique et al. disclose the use of a hydrophobic surface region along an intermediate portion of an otherwise hydrophilic microchannel. For instance, see the location of hydrophobic region (40) illustrated in FIG. 3A of the Handique patent. The hydrophobic surface region is used to regulate flow of a liquid sample between one part of a microchannel structure and another.

The inflow channel of Handique et al. is illustrated as (20) in FIG. 3A and is located at an upstream location along the microchannel relative to the hydrophobic region (40). The patent states that “liquid (shown as a horizontal dashed line) placed at the inlet (20) is drawn in by surface forces and stops in the channel at hydrophobic region (40)”. Thus, the aqueous liquid sample enters the microchannel structure by being automatically drawn into the microchannel by surfaces forces as soon as the liquid sample contacts the inflow channel (20). Thereafter, the hydrophobic region (40) regulates further passage of the aqueous fluid along the length of the microchannel. However, the regulating function of the hydrophobic region occurs only after the aqueous fluid penetrates the microchannel structure. Regions

(50) and (70) illustrated in FIG. 3A of the Handique patent are identified as a gas intake passage and a gas vent passage. Neither is disclosed as an inlet or an inflow channel for an aqueous fluid sample.

Turning to the present application, independent claim 1 has been amended to require the inflow channel to have an inner end communicating with the reaction chamber and an outer end communicating with an exterior of the apparatus. No new matter was added. For example, see FIG. 1A of the present application in which a drop of an aqueous fluid is seated on the outer end of the inflow channel. FIG. 1A also clearly identifies the hydrophobic walls of the inflow channel and illustrates the inner end of the inflow channel interconnecting to the reaction chamber, or “Microreactor”.

The hydrophobic walls of the inflow channel form a hydrophobic gate and prevent entry of an aqueous fluid into the microchannel structure of the apparatus until acted upon by a fluid entry force. Thus, the present invention provides precise control as to when, and if, an aqueous fluid positioned adjacent the inflow channel penetrates and enters the microchannel. A fluid entry force is applied only when a drop of the desired aqueous fluid is properly located adjacent the outer end of the inflow channel. This enables the user to prevent contaminants from entering the microchannel structure and disrupting the assay.

As an example of the present invention, a hydrophobic substrate material can be laminated to a hydrophilic substrate material, and a microchannel structure can be formed therebetween by grooves provided on the engaged surfaces of the substrate materials. The inflow channel can extend transversely through the hydrophobic material and interconnect to the microchannel structure. Thus, the inflow channel has hydrophobic surfaces that prevent an aqueous fluid sample from penetrating into the microchannel. After a fluid entry force is applied, the aqueous fluid sample passes through the inflow channel and is able to readily

pass through the remaining parts of the microchannel since the remaining parts of the microchannel have surfaces provided at least partially by the hydrophilic substrate material.

A claim of a patent application can be anticipated under 35 USC §102 only if each and every element is found described in a single prior art reference. The identical invention must be shown in as complete detail as contained in the claim. The elements identified by the reference must be arranged as required by the claim. If a prior art reference relied on in a rejection made under §102 does not contain every element recited in the claim in as complete detail as is contained in the claim and arranged as recited in the claim, the rejection is improper.

Applicants respectfully submit that the Handique patent fails to disclose the above referenced limitations of claim 1 of the present application. The inflow channel of Handique et al. has a surface that automatically draws an aqueous liquid sample into the microchannel. Thereafter, Handique et al. regulate flow of the liquid by a hydrophobic region positioned at an intermediate portion of the microchannel such that flow is regulated between one part of the microchannel and another. Handique et al. fail to disclose a hydrophobic inflow channel that communicates with the exterior of the apparatus and that prevents entry of an aqueous fluid into the microchannel until acted upon by a fluid entry force.

Accordingly, Applicants respectfully submit that the §102 rejection is unsupported by Handique et al. and should be withdrawn.

## II. Claim Rejections - 35 USC §103(a)

- A. In the Office Action, the Examiner rejects claims 9, 10, 60-63 and 65-71 under 35 USC §103(a) as being obvious over U.S. Patent No. 6,130,098 issued to Handique et al.

Significant differences between claim 1, as amended, of the present application and Handique et al. are discussed above in detail. The inflow channel (20) of Handique et al. has a surface that automatically draws an aqueous liquid sample into the microchannel. A hydrophobic region (40) is located at an intermediate position along the length of the microchannel and regulates flow of a liquid sample from one part of the microchannel to the next. Handique et al. fail to teach, disclose, or suggest an inflow channel that prevents any entry of aqueous fluid into the apparatus and microchannel until a fluid entry force is applied to permit fluid flow through the fluid inflow channel.

For at least these reasons, Applicants respectfully submit that claims 9, 10, 60-63 and 65-71, which all depend directly or indirectly from claim 1, are non-obvious and patentable over the Handique et al. patent.

Applicants also submit that claim 60 is non-obvious and patentable over the Handique patent for an additional reason. Claim 60 requires a substrate made of hydrophobic material. The inflow channel for an aqueous liquid sample is formed and extends transversely through the hydrophobic substrate so that the walls of the inflow channel are hydrophobic. In Handique et al, the hydrophobic regions are formed by chemical modification of surfaces of a microchannel and not by creating a channel that extends transversely through a hydrophobic substrate. Therefore, reconsideration of the rejection of claim 60 is also requested for this additional reason.

B. In the Office Action, the Examiner rejects claims 16, 19, 22, 23, 25-29, 31, 33, 36, 38, 41, 42, 44, 46, 54, 58, 64, 72-89 and 92-96 under 35 USC §103(a) as being obvious over U.S. Patent No. 6,130,098 issued to Handique et al. in view of U.S. Patent No. 6,709,869 B2 issued to Mian et al.

As discussed above, Handique et al. discloses the use of a hydrophobic region (40) located at an intermediate position within a microchannel to regulate the flow of a liquid sample from one part of the microchannel to the next. With respect to Mian et al., the Examiner states that it discloses a radially-configured analytical microfluidic apparatus that relies on centripetal forces to facilitate transport and processing.

Applicants respectfully submit that there is no motivation expressly stated in either of the above cited references which would cause a person of ordinary skill to think of combining them. Mian et al. fail to disclose the use of a hydrophobic gate region in connection with controlling the transport of liquid samples through a microchannel. Handique et al. fail to disclose a microfluidic apparatus having a radial configuration. In Handique et al., a gas is injected and vented from selected regions of a microchannel to convey liquid samples through the microchannel. Thus, there is no teaching, suggestion, disclosure or motivation for using centripetal forces in Handique et al. to convey liquid samples within microchannels.

Accordingly, Applicants submit that it is improper to combine features described separately in different references without any suggestion in either reference for such a combination. There is simply no fair teaching of the combination in the cited references. Reconsideration is respectfully requested for this reason.

In addition, claim 92, as amended, of the present application is directed to a method in which a drop of a sample of an aqueous solution under test is placed at an outer end of an inflow channel of an apparatus used to perform chemical assays. The inflow channel has hydrophobic surfaces and prevents the passage of the aqueous solution into and through the

inflow channel. Thus, the drop of aqueous fluid remains on the exterior surface of the apparatus and does not enter the microchannel. Only when a fluid entry force is applied is the aqueous solution permitted to enter the microchannel through the inflow channel.

Neither Handique et al. nor Mian et al. disclose the method of claim 92 of the present application. Handique et al. has an inflow channel with surfaces that automatically draw an aqueous fluid into the microchannel. Mian et al. also fails to disclose the use of an inflow channel with hydrophobic surfaces. Accordingly, Applicants submit that method claims 54, 58 and 92-96 of the present application are patentable over the cited references whether or not they are combined.

Similar limitations have also been added to independent claim 1, as previously discussed. Accordingly, Applicants submit that apparatus claims 16, 19, 22, 23, 25-29, 31, 33, 36, 38, 41, 42, 44, 46, 64 and 72-89 of the present application are patentable over the cited references.

Further, apparatus claim 87 has been amended to recite structure limitations, not product-by-process limitations. Thus, claims 87, 40 and 41 require the apparatus to be a lamination of a polymer substrate to an overlying polymer layer. Depressions formed in the substrate define a microchannel structure within the lamination. Claim 41 requires the substrate or overlying layer to be made of polyethylene. Inflow channels can be formed through the polyethylene and provide hydrophobic gates that prevent entry of aqueous fluid into the microchannel structure within the lamination until a fluid entry force is applied. Neither Handique et al. nor Mian et al. disclose such a structure. Accordingly, claims 40, 41 and 87 are submitted as being patentable over the cited combination of references for these additional reasons.

### III. Conclusion

In view of the above amendments and remarks, Applicants respectfully submit that the rejections have been overcome and that the present application is in condition for allowance. Thus, a favorable action on the merits is therefore requested.

Please charge any deficiency or credit any overpayment for entering this Amendment to our deposit account no. 08-3040.

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